

Medeor Therapeutics Completes Enrollment in CIRM-Funded Clinical Trial for Kidney Transplant Patients

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Oakland, CA – A CIRM-funded clinical trial to help kidney transplant patients avoid the need for anti-rejection or immunosuppressive medications has completed enrollment and transplantation of all patients.

Medeor Therapeutics' MDR-101 Phase 3 multi-center clinical trial involved 30 patients; 20 of them were treated with MDR-101, and 10 control subjects were given standard care. CIRM awarded Medeor, based in South San Francisco, \$18.8 million for this research in January 2018.

More than 650,000 Americans suffer from end-stage kidney disease - a life-threatening condition caused by the loss of kidney function. For these people the best treatment option is a kidney transplant from a genetically matched, living donor. Even matched patients, however, face a lifetime on immunosuppressive drugs to prevent their immune system from rejecting the transplanted organ. These drugs can be effective at preventing rejection, but they come at a cost. Because they are toxic these medications increase a transplant patient's life-time risk of cancer, diabetes, heart disease and infections.

Medeor Therapeutics developed its MDR-101 therapy to reprogram the patient's immune system to accept a transplanted kidney without the need for long term use of immunosuppression drugs.

The company takes peripheral blood stem cells from the organ donor and infuses them into the patient receiving the donor's kidney. This creates a condition called "mixed chimerism" where immune cells from the donor help the patient's immune system adapt to and tolerate the donor's kidney.

After a standard kidney transplant, the patient is given a combination of three anti-rejection medications which they typically have to remain on for the rest of their lives. However, the Medeor patients, by day 40 post-transplant, are only taking one medication and the hope is that immunosuppression is discontinued at the end of one year.

"Chronic kidney disease and kidney failure are a growing problem in the US, that's why it's so important that we find new ways to reduce the burden on patients and increase the odds of a successful transplant with long term benefit," says Maria T. Millan, M.D., President and CEO of CIRM. "Medeor's approach may not only reduce the likelihood of a patient's body rejecting the transplanted organ, but it can also improve the quality of life for these people and reduce overall health care costs by eliminating the need to stay on these immunosuppressive medications for life."

In an earlier Phase 2 trial, a majority of patients achieved mixed chimerism. Approximately 74 percent of those patients have been off all immunosuppressive drugs for more than two years, including some who continue to be off immunosuppressive medications 15 years after their surgery.

"Today's news is a tremendous milestone not only for Medeor but for the entire transplant community. This is the first randomized, multi-center pivotal study designed specifically to stop the use of all immunosuppressive anti-rejection drugs post-transplant. This therapy can be a true game changer in our efforts to transform transplant outcomes and help patients live healthier lives," said Dan Brennan, MD, Chief Medical Officer at Medeor Therapeutics.

If the results from this pivotal clinical trial show that MDR-101 is both safe and effective, Medeor may apply to the Food and Drug Administration (FDA) for approval to market their approach to other patients in the U.S.

About CIRM

At CIRM, we never forget that we were created by the people of California to accelerate stem cell treatments to patients with unmet medical needs, and act with a sense of urgency to succeed in that mission.

To meet this challenge, our team of highly trained and experienced professionals actively partners with both academia and industry in a hands-on, entrepreneurial environment to fast track the development of today's most promising stem cell technologies.

With \$5.5 billion in funding and more than 150 active stem cell programs in our portfolio, CIRM is the world's largest institution dedicated to helping people by bringing the future of cellular medicine closer to reality.

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